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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,097	10/30/2003	Lotien Richard Huang	10434/60901	2657
26646	7590	12/13/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			FICK, ANTHONY D	
			ART UNIT	PAPER NUMBER

1753

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,097

Applicant(s)

HUANG ET AL.

Examiner

Anthony Fick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

1. Applicant's amendments to the claims have overcome the previous rejections under 35 U.S.C. 112 second paragraph. Applicant's arguments, see pages 8 and 9, with regards to the rejection under 35 U.S.C. 112 first paragraph have been considered and found to be persuasive. Applicant's specification does disclose at least one method for making and using the claimed invention and thus the rejection under 35 U.S.C. first paragraph is withdrawn. However, the examiner still notes that the electric field lines shown in figures 5, 9B, 10, 11 and 12 do not match the expected field lines for the parallel bar electrodes used within the figures to create the electric field.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiktorowicz et al. (U.S. 6,214,191).

Wiktorowicz discloses an integrated microfluidic device as seen in figures 3 and

4.

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Regarding claim 1, the device comprises a microfluidic channel, 170, with an inlet and an outlet and a sample chamber, 160 and 180, comprising a first and second electrode, 130a and 132a, capable of generating a first electric field within the sample chamber wherein the electric field transfers charged molecules in the sample chamber to the inlet of the channel. Figure 4 further shows a fluid reservoir, 140, connected to the sample chamber by the micro-fluidic channel and comprising a third electrode capable of generating a second electric field with at least the second electrode (column 15, paragraph 2).

Regarding claim 5, Wiktorowicz further discloses the use of a polymer matrix material within the sample chamber to provide a pH gradient. The electric field elutes the charged molecules out of this polymer matrix.

Regarding claims 2 through 4, 6, 7, 9 and 10, Wiktorowicz discloses use of the device for several different samples (column 12, paragraphs 2 and 3).

Regarding claim 13, the device can contain a third electrode in the sample chamber, the dotted line in figure 3 (column 15, paragraph 2).

Regarding claim 15, the device can also be interpreted in an alternate view. Figures 3 and 4 also show the device comprises a microfluidic channel, 180, with an inlet and an outlet and a sample chamber, the area from 160 to 140, comprising a first and second electrode, the electrode in 140 (column 15, paragraph 2) and 132a, capable of generating a first electric field within the sample chamber wherein the electric field transfers charged molecules in the sample chamber from the outlet of the channel. Figure 4 further shows a fluid reservoir, 130, connected to the sample chamber by the

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micro-fluidic channel and comprising a third electrode, 130a, capable of generating a second electric field with at least the second electrode.

Regarding claim 20, Wiktorowicz further discloses the use of a polymer matrix material within the sample chamber and the electric field transferring the molecules from the outlet of the channel and into the matrix material (column 16, paragraph 3).

Regarding claims 16, 17, 19, 21, 22 and 24, Wiktorowicz discloses use of the device for several different samples (column 12, paragraphs 2 and 3).

The alternate interpretations of Wiktorowicz are based on applicant's definition of the sample chamber, a well, reservoir or cavity which contains a fluid medium and may comprise two or more compartments, inter-connected by one or more channels (specification paragraph 0036). In interpretation 1 of Wiktorowicz, the sample chamber includes the compartments 130 and 160 inter-connected by the channel 180. In interpretation 2, the sample chamber includes the compartments 160 and 140 inter-connected by the channels 170. In view of applicant's definition of the sample chamber, both interpretations of Wiktorowicz are reasonable and the prior art is used for the rejections stated above.

4. Claims 15 through 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mathies et al. (U.S. 6,361,671).

Mathies discloses an integrated microfluidic device in figure 1.

Regarding claim 15, the device comprises a microfluidic channel, 12, with an inlet and outlet, a sample chamber at the outlet of the channel, 13, comprising a first electrode, 17, 18 or working electrodes 1 through 4 and a second electrode 16, capable

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of generating an electric field, the electrodes inherently transferring the charged molecules from the outlet and into the sample chamber onto the working electrodes. The device also contains a fluid reservoir, 23, at the inlet of the channel, and comprises a third electrode capable of generating a second electric field with the second electrode (dotted lines in the figure).

Regarding claims 16 through 19, a variety of samples are utilized (column 5, paragraph 6).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8, 11, 12, 14, 18, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz as applied to claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24 above, and further in view of Adcock (U.S. 4,959,133).

The disclosure of Wiktorowicz is as stated above for claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24.

The differences between Wiktorowicz and the claims are the requirements of a specific matrix material, and inverted electric pulses.

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Adcock teaches a method of field inversion electric pulses to force DNA or protein out of a gel and into an appropriate receiver (abstract). This method allows for the elution of higher molecular weights as in claims 8, 18 and 23.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the gel plugs and method of elution of Adcock within the device of Wiktorowicz because the plugs and method allow for elution of higher molecular weights in shorter times. Also agarose is a common material utilized for electrophoresis and it would be obvious to use for the gel plugs as in claims 12 and 26. Because Wiktorowicz and Adcock are both concerned with electrophoretic separation products, one would have a reasonable expectation of success from the combination. Thus the combination meets the claims.

7. Claims 11, 12, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz as applied to claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24 above, and further in view of Gautsch (U.S. 6,162,602).

The disclosure of Wiktorowicz is as stated above for claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24.

The difference between Wiktorowicz and the claims is the requirement of a specific matrix material.

Gautsch teaches an apparatus and method for nucleic acid base sequencing. Gautsch further teaches that capillary gel electrophoresis employing agarose or polyacrylamide gels is used to separate fragments (column 3, paragraph 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize agarose gels as in Gautsch within the device of Wiktorowicz because the agarose gel is an improved method over slab gel and agarose is a functional equivalent to the polyacrylamide utilized within Wiktorowicz (Gautsch column 3, paragraph 1). Because Wiktorowicz and Gautsch are concerned with separating fragments, one would have a reasonable expectation of success from the combination. Thus the combination meets the claims.

Response to Arguments

8. Applicant's arguments filed September 21, 2006 have been fully considered but they are not persuasive. Applicant argues that the device of Wiktorowicz does not meet the requirements of the claims by not having two electrodes within the sample chamber or a third electrode capable of generating a second electric field. The examiner respectfully disagrees. As stated within the rejections above, Wiktorowicz does disclose a third electrode that produces a second electric field, the electric field that actually carries out the separation within the plurality of channels. The electrode is not shown in the figures, however it is disclosed within the method of carrying out separations using the device. Without a third electrode, the device would not work as separating in two dimensions. Also as stated above, the electrodes in Wiktorowicz are within the sample chamber as defined by applicant, a well, reservoir or cavity which contains a fluid medium and may comprise two or more compartments, inter-connected by one or more channels (specification paragraph 0036). In interpretation 1 of Wiktorowicz, the sample chamber includes the compartments 130 and 160 inter-connected by the channel 180.

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In interpretation 2, the sample chamber includes the compartments 160 and 140 interconnected by the channels 170. In view of applicant's definition of the sample chamber, both interpretations of Wiktorowicz are reasonable and the prior art is used for the rejections stated above.

Applicant also argues that the device of Mathies does not meet the requirements of the claims as the detection reservoir is not a sample chamber. The examiner respectfully disagrees. As defined by the applicant, the sample chamber is a well, reservoir or cavity which contains a fluid medium. Cavity 13 in figure 1 of Mathies meets the structural requirements and is thus a sample chamber. While it may be called something else, the device meets all the structural limitations of the claims and thus the rejection is maintained.

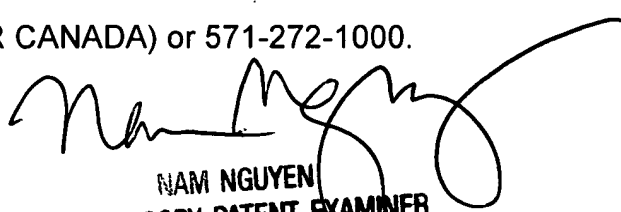
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Fick whose telephone number is (571) 272-6393. The examiner can normally be reached on Monday thru Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anthony Fick *ADF*
AU 1753
December 8, 2006


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